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10/821,981	04/12/2004	Seth Orlow	ORLOW1A	3666
1444	7590	04/28/2009		
BROWDY AND NEIMARK, P.L.L.C.			EXAMINER	
624 NINTH STREET, NW			BROWN, COURTNEY A	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/821,981	Applicant(s) ORLOW ET AL.
	Examiner COURTNEY BROWN	Art Unit 1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 12 January 2009.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-25 is/are pending in the application.

4a) Of the above claim(s) 4-25 is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-3 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) Information Disclosure Statement(s) (PTO/0256/06)
Paper No(s)/Mail Date _____

4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____

5) Notice of Informal Patent Application

6) Other: _____

DETAILED ACTION

Acknowledgement of Receipt/Status of Claims

This Office Action is in response to the amendment filed January 12, 2009.

Claims 1-25 are pending in the application. Claim 1 has been amended. Claims 4-25 have been withdrawn as being directed to a non-elected invention. Claims 1-3 are being examined for patentability.

Applicant's arguments, see pages 18-20, filed January 12, 2009, with respect to the rejection(s) of claim(s) 1-3 under 35 USC 103 (a) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection has been made below.

Applicant's arguments, see pages 18-20, filed January 12, 2009, with respect to the obviousness-type double patenting rejection(s) of claim(s) 1-3 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection has been made below.

Rejections not reiterated from the previous Office Action are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of rejections and/or objections presently being applied to the instant application.

New Rejection(s)

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-3 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 11/408,108 in view of Orlow et al. (WO 02/098347) and Greenspan et al. (*Archives of Dermatology*). Although the conflicting claims are not identical, they are not patentably distinct from each other because the instantly claimed subject matter embraces or is embraced by the co-pending application 11/408,108.

Copending claim1 teaches the same method of screening compounds that inhibits pigmentation through determining the increase of tyrosinase. The difference

between the instant application and copending Application No. 11/408,108 is that the instant application claims the use of a trisubstituted triazine compound that interacts with mitochondrial ATPase. However Orlow et al. teach that a pharmaceutical effective amount of compounds such as baflomycin or concanamycin inhibit ATPases which results in an activation of melanogenesis (page 13, lines 3-29). Greenspan et al. teach that cutaneous hyperpigmentation developed in two patients with malignant brain tumors following chemotherapy with triazine (a trisubstituted triazine)(see abstract). It would have been obvious to one of ordinary skill in the art to substitute triazine (a trisubstituted triazine) in place of baflomycin or concanamycin because triazine has been taught to cause cutaneous hyperpigmentation and would therefore yield predictable results to one of ordinary skill in the art at the time of the invention.

From this extensive overlap of subject matter, one of ordinary skill in the art would recognize that the same product is produced in the copending application 11/408,108 .

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Orlow et al. (WO 02/098347) in view of Greenspan et al. (*Archives of Dermatology*).

Applicant's Invention

Applicant claims a method for screening for a test compound being selected from the group consisting of trisubstituted triazines that interact with prohibitin or mitochondrial ATPase to determine if the test compound is one that inhibits or stimulates pigmentation comprising: a.) determining the amount of melanin or tyrosinase in cells or extracts of cells; b.) treating the cells with a test compound; and c. determining the amount of melanin or tyrosinase in the treated cells or extracts of cells; d.) wherein a change in the amount of melanin or tyrosinase in the cells or the extract of cells in the presence of the test compound as compared to the absence of the test compound indicates that the test compound is one that affects pigmentation.

***Determination of the scope and the content of the prior art
(MPEP 2141.01)***

Orlow et al. teach methods of screening for compounds that affect melanogenesis and the function of P protein in organisms, cells, or cell-free systems; methods of inhibiting melanogenesis; methods of activating melanogenesis; and compounds useful for the inhibition or activation of melanogenesis and, therefore, for lightening or darkening the pigmentation of cells and tissue, i.e., skin (abstract). Orlow et al. teach a method of activating melanogenesis which comprises contacting a melanocyte with diminished or absent P protein activity with a pharmaceutical effective amount of a compound that inhibits ATPases, whereby the inhibition of ATPases results in an activation of melanogenesis in the melanocyte . In another embodiment, Orlow et

al. teach said wherein a melanocyte with diminished or absent P protein activity is contacted with a pharmaceutical effective amount of a compound selected from the group consisting of baflomycin, concanamycin, and derivatives thereof. In a preferred embodiment, Orlow et al. teach said method wherein the melanocyte with diminished or absent P protein activity is contacted with a pharmaceutical effective amount of baflomycin and concanamycin, or derivatives thereof (page 13, lines 3-29). Orlow et al. teach methods of screening for inhibitors of melanogenesis using assays for tyrosinase protein serve to identify inhibitors of melanogenesis using assays of tyrosinase activity (i. e., the protein's enzymatic activities). Orlow et al. further provide a method of screening inhibitors of melanogenesis using assays for either extracellular or intracellular tyrosinase protein levels wherein, assays for determining tyrosinase protein levels and/or locations are used. Orlow et al. teach, in a non-limiting method of screening for compounds that inhibit melanogenesis wherein melanogenic cells are grown or incubated in medium containing a test compound. The presence, concentration, or amount of tyrosinase in said medium is determined using a protein detection assay. Test compounds that cause said treated cells to secrete more tyrosinase than similar cells grown or incubated under similar conditions without the test compound are candidates for compounds that inhibit melanogenesis (pages 24-25, Section 1.3).

The difference between the invention of the instant application and that of Orlow et al. is that the instant invention claims the use of trisubstituted triazines as opposed to a compound selected from the group consisting of baflomycin and concanamycin. For this reason, the teaching of Greenspan et al. is joined. Greenspan et al. teach that cutaneous hyperpigmentation developed in two patients with malignant brain tumors following chemotherapy with triazinate (a trisubstituted triazine). Greenspan et al. also teach that, for both patients, said hyperpigmentation resolved after the cessation of drug administration and reappeared after the reinstitution of triazinate therapy (abstract).

Finding of prima facie obviousness

Rationale and Motivation (MPEP 2142-2143)

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of the two cited references to arrive at a method for screening for a test compound being selected from the group consisting of trisubstituted triazines that interact with prohibitin or mitochondrial ATPase. The instant claims would have been obvious because the substitution of baflomycin and concanamycin with a triazinate which has been taught to cause cutaneous hyperpigmentation would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

All the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in

their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

Therefore, the claimed invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made because every element of the invention has been fairly suggested by the cited reference.

Response to Arguments

Applicant's arguments, filed January 12, 2009 with respect to the rejection of claim 1 under 35 USC first and second paragraphs have been considered but are moot in view of Applicant's amendment.

Applicant's arguments, filed January 12, 2009, with respect to the 103 rejection of claims 1-3 over Imokawa (July 1989, *Journal of Investigative Dermatology*, 93(1):100-7) in view of Ancans et al. (*Federation of European Biochemical Societies*, 2000) and Hopkins et al. (*Biochemistry*, 2000) have been considered but are moot in view of the new ground(s) of rejection.

The claims remain rejected.

Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR

Only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electron Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Courtney Brown, whose telephone number is 571-270-3284. The examiner can normally be reached on Monday-Friday from 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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